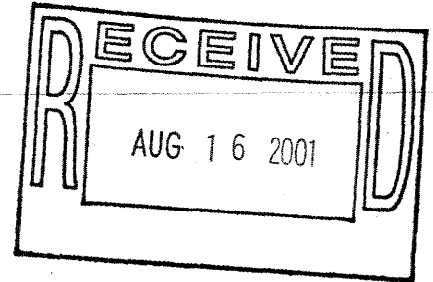




August 8, 2001

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The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, DC 20204



Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

1. Zypan contains betaine hydrochloride to provide the foundation for proper gastric hydrochloric acid production.
2. Zypan also contains proteolytic enzymes in combination with pancreatin, primarily supporting the digestion and absorption of protein.
3. Pancreatin also contains amylase and lipase - necessary for the appropriate breakdown and absorption of carbohydrates and fats.

These statements are made for a dietary supplement containing a proprietary blend of betaine hydrochloride, pancreas Cytosol™ extract, pancreatin (3X), fatty acid, pepsin (1:10,000), ammonium chloride, bovine spleen, and ovine spleen. Other ingredients include cellulose, lactose, and calcium stearate. The name of the product is Zypan®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden  
Standard Process Inc.



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